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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,384	10/29/2003	Mahesh Chaubal	IFT-5657A-1A1C6	8266

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EXAMINER	
OH, SIMON J	
ART UNIT	**PAPER NUMBER**
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/696,384	CHAUBAL ET AL.	
	Examiner	Art Unit	
	Simon J. Oh	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,20,22-26 and 28-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,20,22-26 and 28-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment and response, both received on 16 January 2007.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 19, 21 and 27 under 35 U.S.C. 112, first paragraph, for scope of enablement is rendered moot with the cancellation of these claims.

The rejection of Claims 1-18, 20, 22-26 and 28-46 under 35 U.S.C. 112, first paragraph, for scope of enablement is maintained.

Claim 47 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for itraconazole, budesonide, carbamazepine, prednisolone, nabumetone, does not reasonably provide enablement for other poorly water soluble pharmaceutical compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d

1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention provides methods for producing particles of pharmaceutical compounds having a desired particle size and polymorph by seeding solutions or pre-suspensions of the pharmaceutical compound.

(2) The state of the prior art

Various methods of producing particles of organic compounds such as pharmaceutical agents using precipitation techniques and seeding are known in the prior art. It is generally known in the prior art that the processing parameters of such methods can be manipulated to achieve desired characteristics of such particles, such as size, crystal habit, and polymorphic form.

(3) The relative skill of those in the art

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art

The unpredictability of the art is high, even if the concepts behind particle production of pharmaceutical compounds are known. The particular method steps, in terms of complexity and

number of method steps, for the production of particles of a pharmaceutical compound are required to be specifically tailored to the pharmaceutical compound in question, as well as being tailored for the particular set of desired characteristics, such as size and polymorphic form.

(5) The breadth of the claims

The claims are very broad. The methods claims are drawn to methods of producing particles of any poorly water soluble pharmaceutical compound, with no further limitations given on what sort of solvents and surfactants may be specifically used in the instant claims.

(6) The amount of direction or guidance presented

In the instant specification, the applicant has disclosed several types of techniques for precipitations, such as microprecipitation, emulsion precipitation, solvent/anti-solvent precipitation, phase inversion precipitation, pH shift precipitation, infusion precipitation, temperature shift precipitation, solvent evaporation, reaction precipitation, and compressed fluid precipitation. Additional steps such as seeding and the addition of energy are also disclosed. However, aside from those compounds specifically mentioned in the examples, there is no specific guidance within the instant specification as to which techniques or combination of techniques are suitable for a particular pharmaceutical compound or for producing particles having a particular desired characteristic, such as particle size, range of particle size, or polymorphic form. Thus, there is scant guidance for methods of particle preparation for every conceivable compound that is encompassed by the broad scope of the claims.

(7) The presence or absence of working examples

The instant disclosure does provide working examples, but they are limited to only five pharmaceutical compounds, itraconazole, budesonide, carbamazepine, prednisolone, and

nabumetone. Although the particular steps taken to produce the particles of pharmaceutical compounds are described in sufficient detail, there is no further discussion as to why such steps or combination of steps are needed to produce particles with the desired characteristics. One example (Example 15) is described as a prophetic example, discussing possible steps that may be taken to produce a stable polymorph of an unspecified compound.

(8) The quantity of experimentation necessary

With the lack of specific guidance from the instant specification, the particular combination of method steps which would be suitable for the production of particles of a particular pharmaceutical compound having a particular set of desired characteristics encompassed within the instantly claimed invention cannot be reliably predicted *a priori*. When the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine the proper method steps for each and every pharmaceutical compound that is encompassed within the scope of the instant claims.

Response to Arguments

Applicant's arguments filed 16 January 2007 have been fully considered but they are not persuasive.

The examiner appreciates the applicant's efforts to amend the scope of the instant claims. However, the examiner must maintain the scope of enablement rejection that has been set forth. Although the instant specification presents twenty-five examples, they are all limited to the same five pharmaceutical agents listed above. The examiner finds no fault with the assessment that a large amount of experimentation may not be considered undue if there is sufficient guidance

provided by the disclosure. However, the examiner does not find that there is sufficient guidance to practice the full scope of the instantly claimed invention for all pharmaceutical agents that are poorly soluble in water without an undue level of experimentation. Though the level of one skilled in the art is high, this is merely one of several factors that must be considered in determining rejections based on scope of enablement. Therefore, the pending claims are rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh
Examiner
Art Unit 1618

sjo

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER